



SIGMA-ALDRICH
CORPORATION

2696

3050 Spruce Street
Saint Louis, Missouri 63103 USA
Telephone (800) 521-8956 • (314) 771-5765
Fax (800) 325-5052 • (314) 771-5757
email: sig-ald@sial.com
Visit us at www.sigma-aldrich.com

July 13, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane / Room 1061
Rockville, MD 20852

RE: Comments -- Docket No. 2002N-0278

To Whom It May Concern:

On December 12, 2003, the new section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)) was implemented to support section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). Since that time, Sigma-Aldrich Corporation has experienced numerous delays in clearing our inbound freight through the port of Huntsville, Alabama. We have received several 'Informed Compliance Notices' from U.S. Customs and Border Protection offices. Our customs brokers continue to struggle with our submissions for products that are currently flagged FD3 or FD4. Despite our lengthy attempts to resolve these issues, our sales to U.S. customers for these imported products have suffered and we feel our relationships with both U.S. Customs and our customers have been negatively impacted.

On April 14, 2004, the comment period was re-opened for the prior notice interim final rule (IFR) that was originally published in the Federal Register on October 10, 2003. On May 12, 2004, we submitted a letter to the docket requesting that the FDA flag for several harmonized tariff schedule numbers (HTS) be changed from FD4 to FD3, for the reasons described in this comment letter. In addition to requesting the changes to the FDA flags on specific HTS numbers, we would also like to recommend that the IFR be amended to include an exemption from prior notice for organizations that are importing FD4 materials for non-food uses.

Sigma-Aldrich is a leading Life Science and High Technology company. Its biochemical and organic chemical products and kits are used worldwide in scientific and genomic research, biotechnology, pharmaceutical development, the diagnosis of disease and chemical manufacturing. Our customers are life science companies, universities, government institutions, hospitals and in industry. Over one million scientists and technologists use our products.

Upon reviewing the definitions of 'food' and 'food products' in the FD&C Act, we have determined that only a small number of Sigma-Aldrich products meet this definition and, therefore, would require a prior notice submission under the Bioterrorism Act. The majority of our products do not meet this definition and would not require a prior notice submission. However, several of these non-regulated products are coded with an HTS number that is flagged FD3 or FD4 and there is no exemption process available for us to utilize. For example, we import pre-labeled 1 g vials of Vitamin D in powder form for use in the

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scientific research community. Or, we may import frozen bovine pancreas glands from which we extract specific biochemicals that we then process, package and sell. These materials do not meet the definition of 'food' or 'food product' in the FD&C Act, yet we are being required to submit prior notice entries for these items before we can import this into the U.S.

We appreciate your consideration in this matter and look forward to your response. Please do not hesitate to contact me at the below numbers if you have any questions about this request or if you need additional information.

Sincerely,



Lisa R. Clarke
Director, Corporate Compliance & MSDS
Sigma-Aldrich Corporation

Phone: 314-286-6612
Fax: 314-286-8005
Email: lclarke@sial.com